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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,276	10/20/2003	Daniel Cimbora	1834.01	8598

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EXAMINER	
MOORE, WILLIAM W	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,276	CIMBORA ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-37* is/are pending in the application.

4a) Of the above claim(s) *29-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20060209*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

Applicant's claims in the first page of the specification filed 18 July 2003 to priority under 35 U.S.C. § 119 of the filing dates of several provisional applications and their successor utility applications serial Nos. 09/727,384 filed 1 December 2000, 10/035,343 and 10/035,344, both filed 4 January 2002, 10/099,924 filed 14 March 2002, 10/100,503 filed 18 March 2002, are hereby acknowledged. Table 38, line 29, at page 41 of the parent application serial No. 09/727,384 supports formation of an *in vitro* complex of the integral amino acid regions of PRAK and ERK3 kinases represented in Table 1 at page 18 herein. Example 10, page 29, of application serial No. 60/158,377 filed 2 December 1999 corresponds to the disclosure of Table 38 of serial No. 09/727,384. Thus *in vivo* formation of an PRAK-ERK3 complex comprising the integral 167-amino acid PRAK region and the integral 466-amino acid described by claims 21-28 is accorded the priority of the 2 December 1999 filing date of application serial No. 60/158,377. No parent application discloses adequate conditions, i.e., those disclosed at pages 200-201 of the instant application, for detectable formation of an *in vitro* PRAK-ERK3 complex, which complex has the priority of the 18 July 2003 filing date of the instant application.

Preliminary Amendment

Applicant's Preliminary Amendment filed 6 February 2006 was entered, canceling claims 1-20, presenting new claims 21-37, and correcting the continuing data at page 1 of the specification.

Information Disclosure Statement

Applicant's Information Disclosure Statement [IDS] filed 6 February 2006 is hereby acknowledged and executed copies of the submitted Forms PTO/SB/08 accompany this communication.

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should include language directed to components of the claimed complexes and methods of selection.

Specification

Compliance with 37 CFR § 1.821 is required in response to this Office action. **The elected claims 21-28 lack designations describing their subject matters according to the requirements of 37 CFR § 1.821 for a Sequence Disclosure.** Even if the amino acid sequences of the regions of the PRAK and the ERK3 kinases for which Applicant has established a priority date were set forth in the claims, recitations of a nucleotide or amino acid sequence positions must also include a statement of the designation, "**SEQ ID NO:n**", where "n" is an integer corresponding to the Sequence Disclosure. In addition to the claims, 37 CFR § 1.821 also requires that sequence identifiers, properly stated as "**SEQ ID NO:n**", accompany the descriptions of defined nucleotide and amino acid sequences in the specification, e.g., at pages 18-97 and 197-201, including references to fusion polypeptides having amino acid sequences in the Sequence Disclosure. That sequence identifiers are separately recited at pages 99-104 divorced from any reference to a polypeptide, or encoding polynucleotide, which they might represent cannot constitute compliance. See 37 CFR §§ 1.821(b), (c) and (d).

Restriction/Election

Applicant's Response filed 6 February 2006 to the Requirement for Restriction mailed 4 January 2006, is acknowledged. The Response cancels original claims 1-20 that had been restricted into twelve groups of inventions and presents instead the new claims 21-28 drawn to a bi-molecular complex of two kinases, PRAK and ERK3, and the new claims 29-37, drawn to methods of use of the complex in identifying modulators of

an interaction of the complex components. The Response recognizes that neither set of new claims is drawn to subject matters corresponding to those described by claims of Groups I-XII stated by the Restriction Requirement mailed 4 January 2006. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1. Claims 21-28, drawn to a product that is a bi-molecular kinase complex, classified in class 435, subclass 194.

2. Claims 29-37, drawn to a method of use of a bi-molecular kinase complex in an assay to detect modulators of complex formation, classified in class 435, subclass 15.

Inventions of Groups 1 and 2 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product, such as a process of initiating intracellular transduction of specific kinase activity.

Applicant elects without traverse "the product claims 21-28 for examination" at page 6 of the Response filed 6 February 2006, and reserves the right to have process claims 29-37 "rejoined when the product claims are allowed." Thus claims 21-28 are examined herein and claims 29-37 are withdrawn from consideration as drawn to a non-elected invention. If an occasion for rejoinder arises, further rejections may be required if the method claims 29-37 do not describe structures of components of a PRAK and ERK3 complex commensurate in scope with the structures of PRAK and ERK3 components described by allowable claims to a complex, and Applicant should note the following emphasized advice about retaining the right of rejoinder of non-elected process claims.

Notice of Requirements for Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently

found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented **prior to final rejection or allowance,** whichever is earlier (emphasis supplied). Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). **Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Utility

The threshold of the utility requirement for a claimed product is low. The prior art made of record with Applicant's information disclosure statement, particularly New et al., 1998, identifies PRAK as a useful kinase known to phosphorylate specific targets within mammalian cells. There is no reason to doubt that the ERK3 kinase fragment indicated in Table 1 herein, expressed in host cell, would fail to form a complex with an integral, native, PRAK kinase expressed in a host cell where both comprise the regions indicated in Table 1. The subsequent art made of record with Applicant's Information Disclosure Statement is evidence that such a complex forms. Thus the artisan and the public may form at least the disclosed complex of the claims to isolate a useful PRAK kinase where the integral PRAK kinase may subsequently be dissociated from such a complex, which the specification teaches is stable *in vitro*, and used for a specific purpose.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The broad definition of "interaction" at page 11 of the specification embraces a, "state of proximity between [ ] interaction domains, fragments, proteins or entities [that] may be transient or permanent, reversible or irreversible, [so long as] it is in contrast to and distinguishable from contact caused by natural random movement of two entities [where t]ypically, although not necessarily, an 'interaction' is exhibited by the binding between the interaction domains, fragments, proteins, or entities [and e]xamples of interactions include specific interactions between antigen and antibody, ligand and receptor, enzyme and substrate, and the like". This definition is applied to kinase interaction for the purposes of the following rejections because - unlike specific PRAK and ERK3 fragments of, e.g., claims 25 and 26 not subject to the following rejections - clauses (i) and (1) of claim 21 state no lower limit on the size of a "fragment", wherein, according to clauses (ii) and (2) of claim 21, only three amino acids of a tetrapeptide need be "identical" to corresponding sequences in other kinases or kinase substrates. The following are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Claims 21, 23, 24, 27 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 now prosecuted in copending Application No. 10/035,344. Although the conflicting claims are not identical, they are not patentably distinct from each other because

complexes of the pending claims comprising a structurally undefined "fragment" of PRAK and a structurally undefined "fragment" of ERK3 are indistinguishable from complexes of the similarly structurally undefined fragments of the AKT1 and AKT2 kinases of the co-pending claim, where a "fragment" of either the instant application or the co-pending application may be involved in a kinase interaction and where fusion proteins of claims 23, 24, 27 and 28 herein are also proteins of claim 21 herein and any such fusion protein may include any portions of proteins comprised by the complexes of the co-pending claims.

Claims 21, 23, 24, 27 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 5 now prosecuted in copending Application No. 10/194,385. Although the conflicting claims are not identical, they are not patentably distinct from each other because complexes of the pending claims comprising a structurally undefined "fragment" of PRAK and a structurally undefined "fragment" of ERK3 are indistinguishable from complexes of the similarly structurally undefined fragments of proteins, or proteins, of the co-pending claims, where a "fragment" of either the instant application or the co-pending application may be involved in a kinase interaction and where fusion proteins of claims 23, 24, 27 and 28 herein are also proteins of claim 21 herein and any such fusion protein may include any portions of proteins comprised by the complexes of the co-pending claims.

Claims 21, 23, 24, 27 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 39 and 49 now prosecuted in copending Application No. 10/194,714. Although the conflicting claims are not identical, they are not patentably distinct from each other because complexes of the pending claims comprising a structurally undefined "fragment" of PRAK and a structurally undefined "fragment" of ERK3 are indistinguishable from complexes of the similarly structurally undefined fragments of proteins, or proteins, of the co-pending claims, where a "fragment" of either the instant application or the co-pending application may be involved in a kinase interaction and where fusion proteins of claims 23, 24, 27 and 28 herein are also proteins of claim 21 herein and any such fusion protein may include any portions of proteins comprised by the complexes of the co-pending claims.

Claims 21, 23, 24, 27 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 178 and 194 being prosecuted in copending Application No. 10/194,966. Although the conflicting claims are not identical, they are not patentably distinct from each other because complexes of the pending claims comprising a structurally undefined "fragment" of PRAK and a structurally undefined "fragment" of ERK3 are indistinguishable from complexes of the similarly structurally undefined fragments of proteins, or proteins, of the co-pending claims, where a "fragment" of either the instant

application or the co-pending application may be involved in a kinase interaction and where fusion proteins of claims 23, 24, 27 and 28 herein are also proteins of claim 21 herein and any such fusion protein may include any portions of proteins comprised by the complexes of the co-pending claims.

Claims 21, 23, 24, 27 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21 and 30 being prosecuted in copending Application No. 10/267,476. Although the conflicting claims are not identical, they are not patentably distinct from each other because complexes of the pending claims comprising a structurally undefined "fragment" of PRAK and a structurally undefined "fragment" of ERK3 are indistinguishable from complexes of the similarly structurally undefined fragments of proteins, or proteins, of the co-pending claims, where a "fragment" of either the instant application or the co-pending application may be involved in a kinase interaction and where fusion proteins of claims 23, 24, 27 and 28 herein are also proteins of claim 21 herein and any such fusion protein may include any portions of proteins comprised by the complexes of the co-pending claims.

Claims 21, 23, 24, 27 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24 and 31 being prosecuted in copending Application No. 10/302,799. Although the conflicting claims are not identical, they are not patentably distinct from each other because complexes of the pending claims comprising a structurally undefined "fragment" of PRAK and a structurally undefined "fragment" of ERK3 are indistinguishable from complexes of the similarly structurally undefined fragments of proteins, or proteins, of the co-pending claims, where a "fragment" of either the instant application or the co-pending application may be involved in a kinase interaction and where fusion proteins of claims 23, 24, 27 and 28 herein are also proteins of claim 21 herein and any such fusion protein may include any portions of proteins comprised by the complexes of the co-pending claims.

The preceding provisional obviousness-type double patenting rejections are stated for claims in co-pending applications in which Applicant received a first communication on the merits. Applicant is informed that claims 21, 23, 24, 27 and 28 herein may be provisionally rejected in a subsequent Office Action under the judicially created doctrine of double patenting over one or more claims in at least the copending Application serial Nos. 10/639,017, 10/663,407, 10/859,063, 10/910,237, 10/979,642, 11/005,437, 11/033,462, 11/035,152, 11/041,102, 11/075,234 and 11/171,927 where the commonly-

assigned applications either (1) name one or more members of the inventive entity of the instant application and no election has yet been made to a restriction requirement or (2) have disclosures that would support claims to complexes comprising a kinase fragment. Applicant is therefor required to identify applications that involve either the ERK3 and PRAK kinases of complexes claimed herein or other kinases disclosed to form complexes in protein-protein interactions, and to provide a copy of the pending claims so that the Examiner can determine if any double patenting does, in fact, exist.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection does not affect proteins that comprise the specific, integral, regions of the PRAK and ERK3 kinases described by Table I of the specification. Claims 21-28 are, however, drawn to complexes comprising members of two broad genera of kinase fragments and variants while the specification provides a written description of only one complex that is formed by a specific fragment of a specific PRAK kinase and a specific fragment of a specific ERK3 kinase. No other species are disclosed, suggested, or otherwise structurally described by teachings of the instant specification and neither the specification nor the claims indicate any distinguishing attributes that might be shared by the fragments and variants of the two genera of kinases which include numerous structural variants wherein a significant number of structural differences between genus members is permitted. The specification and claims provide no guidance as to what

changes should be made to amino acid sequences of the specific, integral, PRAK and ERK3 kinase fragments indicated in Table 1 at page 18 and provide no common structural attributes with which to identify members of either genera. The general knowledge and level of skill in the art do not supplement the omitted descriptions because specific, not general, guidance is needed, and the specification fails to provide even general guidance as to modification of the specific, integral, PRAK and ERK3 kinase fragments indicated in Table 1 herein.

In addressing the issue of whether a disclosure of a molecular structure of one polypeptide of one species could adequately describe the molecular structure of a functionally similar molecule of another species, the Court of Appeals for the Federal Circuit held that a claimed invention must be described with such "relevant identifying characteristic[s]" that the public could know that the inventor possessed the invention at the time an application for patent was filed, rather than by a mere "result that one might achieve if one had made that invention". *University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). One skilled in the art cannot reasonably visualize or predict the features which structurally characterize the genera of PRAK kinase and ERK3 kinase components of the claimed complexes because the disclosure fails to describe any common attributes or characteristics that can identify members of these genera. Thus one of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. The specification's treatment of the claimed subject matter is considered to be entirely prospective where skilled artisans in the relevant field of molecular biology could not predict the structure, or other properties, of generic kinases of the claimed complexes.

Claims 21-28 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for the *in vivo* and *in vitro* preparation of an isolated protein complex comprising (i) a native PRAK kinase or fragment thereof comprising the 168-amino acid sequence indicated in Table 1, and (ii) a native ERK3 kinase or fragment

thereof comprising the 466-amino acid sequence indicated in Table 1, as well as enabling the use of such a complex in purifying a native PRAK kinase, does not reasonably provide enablement for preparation of an isolated complex of undisclosed fragments or variants of a native PRAK kinase or a native ERK3 kinase or the use thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection does not affect proteins that comprise the specific, integral, regions of the PRAK and ERK3 kinases described by Table I of the specification. The scope of each of the rejected claims, however, reaches complexes comprised of genera of undisclosed fragments and variants and pages 61-64, 67-69, 98 and 197-201 of the specification teach no more than that a mammalian PRAK kinase and a mammalian ERK3 kinase interact within yeast cells to an extent sufficient for fusion partners present in fusion polypeptides comprising the separate kinase components to generate a phenotype detectable in yeast cells. The specification provides no teaching, or other basis, supporting the introduction of at least 42 amino acid alterations in the amino acid sequence of the disclosed PRAK fragment, nor even a minimal PRAK fragment, nor the introduction of 116 alterations in the amino acid sequence of the disclosed ERLK3 fragment, nor even a minimal PRAK fragment, where amino acid insertions, deletions, or substitutions occur anywhere, in any combination or any pattern, in the disclosed fragments. Indeed, neither the prior art made of record herewith nor Applicant's specification can identify, taken together, any amino acids in the primary sequence of the two disclosed kinase fragments that might be altered, nor teach the nature of an alteration that may be made, which permits a resulting polypeptide or peptide to sustain an "interaction" or remain useful as a kinase. Mere sequence perturbation cannot enable the design and preparation of nucleotide sequences encoding a myriad of divergent protease enzymes and provide the public with a nucleotide sequence encoding an enzyme that retains its native function. This is well demonstrated by the publication of Seffernick et al., 2001, **Journal of Bacteriology**, Vol. 183, No. 8, pages

2405-2410, made of record herewith, who teach that the alteration of 9 amino acids in a sequence of 475 amino acids, a scant 2% of the native amino acid positions, in a deaminase will suffice to alter its substrate specificity and require it to catalyze different reactions even though, p. 2409, these alterations do not at all alter its tertiary structure and are spread throughout its primary structure.

It is well settled that 35 U.S.C. § 112, first paragraph, requires that a disclosure be sufficiently enabling to allow one of skill in the art to practice the invention as claimed without undue experimentation and that unpredictability in an attempt to practice a claimed invention is a significant factor supporting a rejection under 35 U.S.C. §112, first paragraph, for non-enablement. See, *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (discussing eight factors relevant to analysis of enablement). The standard set by the CCPA, the precursor of the Court of Appeals for the Federal Circuit, is not to "make and screen" any and all possible alterations because a reasonable correlation must exist between the scope asserted in the claimed subject matter and the scope of guidance the specification provides. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 25 (CCPA 1970) (scope of enablement varies inversely with the degree of unpredictability of factors involved in physiological activity of small peptide hormone). The Federal Circuit approved the standard set by the CCPA in *Fisher* in *Genentech, Inc. v. Novo-Nordisk A/S*, 42 USPQ2d 1001 (Fed. Cir. 1997). Applying the factors discussed in *Wands* to Applicant's disclosure, it is apparent that:

a) the specification lacks adequate, specific, guidance for altering the amino acid sequences of the disclosed fragments of the PRAK and ERK3 kinases to the extent permitted in the claims,

b) the specification lacks working examples wherein the disclosed fragments of the PRAK and ERK3 kinases are altered to any extent, let alone the extent recited in the claims,

c) in view of the prior art publications of record herein, the state of the art and level of skill in the art do not support such alteration, and,

d) unpredictability exists in the art where no members of the class of kinases represented the disclosed fragments of the PRAK and ERK3 kinases have had even a few amino acids specifically identified for concurrent modification.

Thus the scope of subject matters embraced by the phrase, " fragment thereof . . . at least 75% identical to", is unsupported by the present specification even if taken in combination with teachings available in the prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-28 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claim 21 lacks sequence identifiers for the amino acid sequences of the intended fragments of the PRAK and ERK3 kinases thus claim 21, and claims 22-28 depending therefrom, fail to particularly point out and distinctly claim Applicant's intended subject matter because they do not place the boundaries with which the artisan and the public can identify the basis for determining percentage identity, or even the end of a potential fragment. The claims must identify the context in which intended variations occur in order that there be no ambiguity in determining the metes and bounds of the claimed subject matter. This rejection may be overcome by amending at least claim 21 to insert the absent sequence identifiers for both the PRAK and ERK3 amino acid sequences.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is

571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
28 April 2006

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER